

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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ISLET SCIENCES, INC.,  
:

Plaintiff,  
:

– against –  
:

AVOLYNT, INC., BRIGHTHAVEN VENTURES,  
LLC, WILLIAM WILKISON, and JAMES  
GREEN,  
:

Defendants.  
:  
-----X

19 Civ. 337 (AT)

**SECOND AMENDED COMPLAINT**

**COHEN & GRESSER LLP**

Alexandra Wald  
awald@cohengresser.com  
Francisco A. Villegas  
fvillegas@cohengresser.com  
Marvin J. Lowenthal  
mloenthal@cohengresser.com  
800 Third Avenue, 21<sup>st</sup> Floor  
New York, NY 10022  
Phone: (212) 957-7600  
Fax: (212) 957-4514

*Attorneys for Plaintiff Islet Sciences, Inc.*

Plaintiff, ISLET SCIENCES, INC. (“Islet”), by and through their undersigned counsel, files this First Amended Complaint for relief against Defendants, AVOLYNT, INC. (“Avolynt”), BRIGHTHAVEN VENTURES, LLC (“BHV”), WILLIAM WILKISON (“Wilkison”), an individual, and JAMES GREEN (“Green”), an individual (all collectively, “Defendants”), and alleges, upon knowledge as to its own conduct and upon information and belief as to the conduct of others, as follows:

### **INTRODUCTION**

1. This case is about BHV’s broken promises to Islet that the two companies would jointly develop and share in the profits of a new class of drug (the “Remo Technology”) directed to the treatment of type 2 diabetes and related conditions.

2. In 2012, BHV was financially distressed, burdened with debt, and subject to looming international patent filing deadlines on intellectual property essential to its business, as well as a potential forfeiture of the license pursuant to which BHV had acquired the right to develop the Remo Technology as its likely sole business purpose.

3. At BHV’s request and in reliance on its promises that the parties would partner to develop the Remo Technology, Islet – a biopharmaceutical company focused on acquisition, licensing and development of companies and intellectual property in the field of diabetes and metabolic disorders – provided BHV with: invaluable technical know-how, money, access to Islet’s own expert consultants in the field of diabetes, retention of experienced patent counsel funded by Islet, business strategy, and other support for international patent filings that so far have resulted in numerous issued patents.

4. Islet provided BHV with all these resources based on BHV’s assurances that Islet and BHV would jointly reap the benefits of Islet’s support of, and investment in, the Remo Technology through their shared venture.

5. BHV was fully aware that Islet was contributing money, guidance, time, reputational backing, and patent development support for the express purpose of preserving and developing the Remo Technology, which BHV represented would be a shared asset from which both parties would profit together as business partners.

6. Islet – which was in the business of partnering with promising companies in the field of metabolic disease, and was not a consultancy or service provider – would never have contributed its expertise, intellectual property, time, funds, resources, and goodwill for the benefit of BHV, had BHV not promised Islet partnership and the prospect of shared return.

7. Once BHV had secured its intellectual property using Islet's resources, however, BHV abandoned the promises of a joint venture based on which Islet had enriched BHV, and kept the fruits of Islet's assistance for itself.

8. As a direct result of Islet's actions and support, BHV has now successfully completed Phase II clinical trials and is or will soon be in Phase III clinical trials for the Remo Technology – poising it for vast profits – while Islet currently stands to gain nothing for its many contributions, which directly enabled BHV's success.

### **JURISDICTION AND VENUE**

9. This Court has personal jurisdiction over Defendants under New York Civil Practice Law and Rule 302(a) because Defendants were, or in the case of Avolynt, is the owner and successor of a company that did: (i) transact business in New York and engage in continuous and systematic business in New York and in this District; (ii) contract to supply goods or services in New York in connection with matters giving rise to this suit; and/or (iii) regularly do or solicit business in New York, and/or derive substantial revenue from goods used or services rendered in New York, and/or expect or reasonably should expect their conduct to have consequences in New York and derive substantial revenue from interstate commerce.

10. Pursuant to 28 U.S.C. § 1332(a)(1), this Court has subject matter jurisdiction over these claims as the claims arise between citizens of different states and the matter in controversy exceeds \$75,000.

11. Defendants are all citizens of North Carolina, and in the case of the corporate entities, citizens of both North Carolina and Delaware.

12. Plaintiff is a citizen of Nevada and Florida, based on direction and control, as of the filing of the original Complaint through today's filing, as set forth below. While Plaintiff Islet maintained an office in North Carolina during a past period while it was under the control of Defendants Wilkison and Green (North Carolina residents), they were removed as directors in September 2015 and Islet is neither incorporated nor operated, directed or controlled in North Carolina, or otherwise has its primary place of business or headquarters in that state.

13. Pursuant to 28 U.S.C. § 1391(b)(2), venue is proper in the Southern District of New York because a substantial part of the acts, omissions and events giving rise to Plaintiffs' claims occurred in the Southern District of New York.

### **THE PARTIES**

14. Islet is a company that is engaged in research, development, and commercialization of treatments for metabolic disease. The company is also developing diagnostic products to better enable patients and their physicians to understand disease diagnoses and progression. Islet does not operate any manufacturing facilities or engage in retail product sales. Islet shareholders and consultants are located in different states.

15. Islet is a company organized under the laws of the State of Nevada.

16. Since March 2018, Islet's sole board member and officer has been John Steel, its founder, who currently exercises primary direction and control of Islet day-to-day.

17. Mr. Steel has been domiciled at 1001 South Point, Miami, Florida since January 2018.<sup>1</sup> Prior to that time, he resided at 6692 La Jolla Scenic Dr., La Jolla, California,<sup>2</sup> though he also traveled to Florida and New York.

18. With Mr. Steel now domiciled in Florida, the preponderance of decision making and control of Islet occurs from that state. For example, in the last six months, Mr. Steel, from his Florida home, has: (1) conducted negotiations with a major diagnostic company regarding diabetes testing; (2) evaluated manufacturers for a company product; and (3) directed company licensing initiatives. Additionally, Mr. Steel participated in Islet's most recent board meeting (at a time when there were additional board members) telephonically from his Florida home. Based on the aforementioned decision making and control exercised from Florida, Islet is a citizen of that state for purposes of diversity jurisdiction, in addition to being a citizen of Nevada, its state of incorporation.

19. Mr. Steel also spends significant time conducting Islet business in New York. During visits to New York in the six months prior to filing this Action, Mr. Steel has conducted significant business activities, including strategic corporate decision making, meeting with potential investors, and managing intellectual property relationships. While Islet maintained an office in New York at the time of the relevant events in this action, Mr. Steel now conducts much of Islet's business when in New York from the offices of a financial advisor to Islet, Cova Capital Partners, located in Syosset, New York, which permits Islet to use its space for that purpose when Mr. Steel is in New York.

20. The Defendant entities are related businesses with overlapping owners and executives.

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<sup>1</sup> John Steel's Responses to BHV's First Set of Interrogatories, ¶1. (NC Action ECF No. 171).

<sup>2</sup> Answers to the Third-Party Complaint, at 11. (ECF No. 113).

21. Defendant Avolynt is a corporation organized under the laws of Delaware, and is a privately-owned drug development company with its headquarters and principal place of business at 3200 E. Highway 54, Suite 100, Research Triangle Park, North Carolina 27709. Its management team consists of Green as the Chief Executive Officer, Wilkison as the Chief Scientific Officer, Bentley Cheatham (former Chief Executive Officer of BHV) as the Vice President of Research and Development, and Steve Delmar as the Chief Financial Officer (former Chief Financial Officer of Islet). On information and belief, Avolynt is the current assignee of Green and Wilkison's patents related to the Remo Technology.

22. Defendant BHV is a limited liability company organized under the laws of North Carolina, and is a privately-owned pharmaceutical research and development company with its headquarters and principal place of business at 3200 East Hwy 54, Suite 100, Research Triangle Park, North Carolina 27709. According to a press release by Avolynt on Avolynt's website, BHV is also a wholly owned subsidiary of Avolynt (a Delaware corporation, the principal place of business of which is located in North Carolina), thus Avolynt is BHV's only member. Prior to Avolynt's acquisition of BHV, according to public filings, BHV's sole members were Green and Wilkison, both residents of North Carolina..

23. Defendant Green is a former chief executive officer of BHV, and the current chief executive officer of Avolynt. Green is a resident of North Carolina and is listed as an owner of all patents and applications at issue in this suit.

24. Defendant Wilkison is a former Chief Scientific Officer of BHV, and the current Chief Scientific Officer of Avolynt. Wilkison is a resident of North Carolina and is listed as an owner of all patents and applications at issue in this suit.

25. BHV's 2016-2018 annual reports to the North Carolina Secretary of State, and the North Carolina Secretary of State website as of the time this action was commenced, show only two company officials, Green and Wilkison.

26. Avolynt, through BHV, holds an exclusive license to intellectual property underlying the Remo Technology for the global territory outside of Japan, Korea, and Taiwan.

### **BHV'S FORMATION AND ACQUISITION OF REMO TECHNOLOGY**

#### **BHV is Formed to License Remo From Kissei**

27. Wilkison and Green formed BHV in August 2009 specifically for the purpose of developing and marketing the Remo Technology, a diabetes treatment using the molecule Remogliflozin ("Remo") and its salt carrier ("Remo Etabonate").

28. Remo is a highly selective inhibitor of sodium glucose co-transporter 2 ("SGLT2"), which is a protein found in the kidney that is largely responsible for the reabsorption of glucose from the urine.

29. Current diabetes treatments have many drawbacks, including tolerability issues, weight gain, and loss of efficacy over time. Accordingly, there remains a vast unmet need for new oral, insulin-independent diabetes therapies.

30. SGLT2 inhibitor drugs like the Remo Technology show potential to be the only oral diabetes therapies that will safely provide glycemic control with significant weight loss through an insulin-independent mechanism of action, unlike all the diabetes drugs already on the market.

31. The Remo Technology also has huge economic value due to its unique potential to treat Non-Alcoholic Steatohepatitis ("NASH"). Currently, there is no treatment on the market for NASH, which is thought to affect 3 to 12 percent of the United States population.

32. Wilkison became aware of the Remo Technology while working from 2002 to 2009 at GlaxoSmithKline (“GSK”). GSK had licensed the Remo Technology from a Japanese company called Kissei Pharmaceutical Co., Ltd. (“Kissei”), in 2002, but ended its clinical development efforts in 2009 after it failed to identify a commercially viable delivery system.

33. Following GSK’s termination, in October 2009, as described in public filings, Kissei entered into an “Option Agreement” with BHV to license the Remo Technology. The Option Agreement was in conjunction with a license agreement, signed in December 2010, that granted BHV the exclusive right to develop and market the Remo Technology worldwide, except for Japan, Korea, and Taiwan, where Kissei retained the right to develop and market this drug for itself (the “Kissei License”).

34. Again as described in public filings, the Kissei License imposed significant financial and development pressure on BHV by requiring “milestone payments” at different stages of development and regulatory approval. As such, the Kissei License required BHV to make progress in developing the Remo Technology.

#### **The BHV Remo Patents**

35. On July 9, 2010, Wilkison and Green filed U.S. provisional patent application 61/362,946 titled COMBINATION IMMEDIATE / DELAYED RELEASE DELIVERY SYSTEM FOR SHORT HALF-LIFE PHARMACEUTICALS INCLUDING REMOGLIFLOZIN, covering a “biphasic” delivery formulation for Remo, which was designed to release the pharmaceutical compound at different rates (the “Remo Formulation”).

36. If BHV succeeded in obtaining a patent on its proposed delivery system for the Remo Technology, it would have taken an important first step towards meeting its obligations under the Kissei License and commercializing the Remo Technology. If BHV could not obtain patent protection for a delivery system, however, there would be no reason for BHV, much less



an outside investor, to undertake the expense of clinical trials. Like GSK, BHV might have been forced to terminate its license, or been terminated by Kissei.

37. Green and Wilkison did not file a U.S. patent application within the one year time frame afforded by the provisional patent application.

38. Instead, on July 7, 2011 – two days before the provisional patent was about to expire – Green and Wilkison procured nearly an additional two years in which to try to obtain protection for the Remo Formulation, by filing a Patent Cooperation Treaty (“PCT”) application.

39. A PCT application allows the filer to initiate the patent process for a large number of countries simultaneously via a single international filing, after which the filer must proceed to a “national phase” stage of the process, in which each individual country’s patent office makes an ultimate determination as to patentability in that country.

40. While BHV gained extra time by filing the PCT application, however, that time came at a great burden and expense. To enter the national phase stage, the patent filer must take a number of actions simultaneously by a certain date, including hiring local patent lawyers in each country, filing patent papers in multiple patent offices, paying fees to multiple nations, obtaining translations (in some jurisdictions), and tracking deadlines and patent office communications for the applications at once.

41. Pursuant to the PCT application requirements, Green and Wilkison had only until January 9, 2013 (or February 9, 2013, for some of the countries countries), to accomplish all the necessary tasks required to enter the national phase in each country.

42. If they failed to do so, they would lose the chance to protect the Remo Formulation and related intellectual property, and likely the Kissei License to all of the Remo Technology.

**BROKE AND OUT OF TIME, DEFENDANTS ASK ISLET TO  
COLLABORATE ON DEVELOPING REMO**

43. With time quickly running out on their patent rights, and saddled with the expenses of that process, obligations related to the Kissei License, and its other costs of doing business, BHV sought to raise capital and find partnership opportunities.

44. BHV engaged a banker, Stifel Financial Corp. (“Stifel”), to assist with BHV’s increasingly desperate search for capital. Though Stifel approached Eli Lilly and Co. and made other efforts on behalf of BHV, it failed to raise any capital for BHV. Ultimately, Stifel was unable to interest any biotechnology or pharmaceutical company in a business venture, or otherwise to find any solution to BHV’s dual, and urgent, needs for money and a commercialization partner.

45. With their first effort to find a partner and raise capital having failed, Wilkison and Green next sought the help of yet another consultant, Eric Cheng (“Cheng”), who was the Head of Healthcare Investment Banking with the Maxim Group (“Maxim”), located in New York City.

46. Cheng had performed services for Islet in the past, and in mid-2012 he introduced Islet’s Steel to Wilkison and Green.

47. By this point, with less than a year remaining to enter the national phase stage for the PCT application, BHV’s need for funding had reached the point of desperation.

48. As described in public filings, BHV owed approximately \$305,000 to the North Carolina Biotechnology Center, a business development entity that provides funding to fill gaps in technology development and company growth.

49. As described in public filings, BHV also owed Kissei in excess of \$700,000 for un-reimbursed clinical development work that Kissei had undertaken – a payment that BHV had no prospect of making.

50. Money at BHV was so tight that Wilkison and Green could not even afford air fare to carry out BHV business. They had to ask Steel to pay for their airplane tickets from North Carolina to New York City for their first in-person meeting in July 2012. Similarly, they asked Steel to help them pay for the cost of their travel to Japan to meet with Kissei.

51. Islet, by contrast, offered the reputational, intellectual, and financial resources, as well as the access to capital, that BHV needed.

52. Islet (including through its predecessor) had been in business since 1994, and was actively seeking partners to develop diabetes and metabolism drugs.

53. In March 2012, Islet acquired DiaKine Therapeutics, Inc., a biopharmaceutical company focused on diabetes drugs.

54. Also in March 2012, Islet's Scientific Advisory Board was joined by Dr. Christian Mende, a Clinical Professor of Medicine at the University of California, San Diego, who published extensively in the fields of metabolic disease.

55. In May 2012, Islet entered into a license with Yale University to acquire an exclusive license to technology patented by Yale, and entered into a license for patented technology with the Winthrop University Hospital in July 2012.

56. As of August 2012, Islet was also close to completing a license agreement with the University of California, Los Angeles for another diabetes-related invention (this deal was publicly announced in September 2012).

57. Islet's Form 10-Q for the quarter ending July 2012 showed a cash position of \$2.5M, sufficient for at least one year of operations, not taking into account additional capital raises, and almost 53 million shares outstanding, with almost 50 million more shares authorized that could have been issued to raise additional funds. Islet was a public company and had financed its operations primarily through sale of shares.

58. Overall, Islet demonstrated the capacity to provide not only money, but access to the additional funding that BHV had proven itself unable to raise, together with the needed commercialization expertise and a going business in the field of diabetes drug development.

59. Based on all the benefits that Islet could offer, BHV indicated that it was highly interested in partnering with Islet to jointly develop and commercialize products based on the Remo Technology, and the parties negotiated on terms for such a partnership.

60. Islet explained to BHV that its business model was to actively develop and commercialize diabetes drugs, and that it was interested in a collaboration. BHV decided to proceed on that basis.

61. Specifically, on Thursday, August 9, 2012, Cheng emailed Green and advised him of an upcoming Islet board meeting. "Assuming you and Bill [Wilkison] would like to proceed," Cheng wrote, "we would like to agree on terms in advance and have you meet the Board then."

62. Green responded, "that sounds like a good plan." and asked to speak the following Monday.

63. That Monday evening, August 13, 2012, Cheng sent Green a draft term sheet for an Islet-BHV joint venture, to aid in "agree[ing] on terms in advance."

64. The next morning, Green replied, copying BHV's Wilkison, and stated "Let's move forward and plan for a successful Board presentation on Monday."

65. “That’s great news,” Cheng replied to Green and Wilkison, “As per our discussion, can you send over the term sheet with the changes accepted and also an updated date?”

66. Green replied “see attached,” and attached BHV’s “agreed on” term sheet for the partnership between Islet and BHV (the “Term Sheet,” attached hereto as Exhibit 1).<sup>3</sup>

67. Significantly, the Term Sheet reflected the enormous value that BHV placed as of August 2012 on Islet’s financial and other contributions.

68. The Term Sheet reflected an intent for the two companies to partner in a new joint venture.

69. BHV was to contribute the exclusive license that BHV held from Kissei to a limited liability company that would be created to carry out the business of the venture, the purpose of which was to jointly develop drugs based on the Remo Technology.

70. Islet was to contribute capital and project management as well as other development and commercialization support.

71. The LLC was also to assume BHV’s milestone payments and royalty obligations to Kissei as well as BHV’s debt to the North Carolina Biotechnology Center.

72. In exchange for capital and project management, Islet was to receive an **80 percent** ownership interest in the new venture, and would consequently receive **80 percent** of all membership distributions.

73. The Term Sheet also provided that Islet would offer executive positions to Green and Wilkison.

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<sup>3</sup> As reflected by the request for an “updated date,” the Term Sheet bears the erroneous date August 14, 2010, rather than August 10, 2012, when it was sent. The parties had not yet met or discussed any business partnership in 2010.

74. Though purporting to be “non binding” and to impose “no obligations” on the parties itself, the Term Sheet set out the material terms of a joint venture between Islet and BHV to commercialize Remo via a limited liability company to be formed by the two companies for that purpose, under which BHV would sub-license rights under the Kissei License. The Term Sheet also provided that “The parties will negotiate in good faith additional customary and reasonable terms and conditions as part of the Agreement.”

75. Shortly after receiving the Term Sheet back from Green “with the changes accepted” on behalf of BHV, Cheng sent it to Islet’s counsel, noting “the business terms have been agreed.”

76. Having met the condition for attendance by “agree[ing] on terms in advance,” Wilkison and Green proceeded to attend the meeting of Islet’s Board on August 20, 2012, to discuss the Remo Technology and the agreed terms of a joint venture laid out in the Term Sheet.

77. On October 4, 2012, Cheng sent Green and Wilkison the “proposed limited liability company agreement,” copying Steel.

78. The limited liability company agreement stated that the purpose of the new company would be “to collaborate in development and commercialization of products” covered by the Kissei license to BHV.

79. The limited liability company agreement provided that the members of the liability company would share in both the profits and the losses of the venture, and that Islet would contribute capital and the company would assume liabilities of BHV.

80. Management was to be by a board comprised of five directors, with each member having a right to appoint two directors and the fifth director to be mutually appointed by Islet and BHV together.

81. As had been specified in the Term Sheet, Islet would own 80 percent of the equity of the new venture, and BHV 20 percent.

82. Islet's board of directors met again on October 15, 2012, and approved moving forward with the BHV transaction, including hiring Green and Wilkison as executives at Islet, as described in the Term Sheet, with the expectation that they would, among other things, oversee the critical Stage 2 trials for which Islet was to have project management, funding and other responsibilities.

83. Following the meeting, BHV traveled to Japan to obtain Kissei's approval for the deal.

#### **ISLET MANAGES AND FUNDS DEVELOPMENT OF THE REMO PATENTS**

84. By October 2012 at the latest, Islet began performing its obligations and taking steps for the benefit of the agreed partnership, including assuming management of and funding the development of the Remo Technology, and bearing expenses of the joint venture related to the Remo Technology, often without any contribution to either by BHV.

85. For example, Islet replaced the law firm that BHV had hired to prosecute the Remo Formulation PCT application (PCT/2011/043143) with Islet's own choice of patent counsel, J.A. Lindeman & Co. PLLC ("Lindeman PLLC"), and began incurring legal expenses on behalf of the venture to develop BHV's Remo Formulation patents as part of an overall strategy in support of the joint venture's future business.

86. Islet directed Lindeman PLLC and otherwise managed the worldwide prosecution of the Remo Formulation patents, including strategizing how to address problems that had emerged such as with BHV's corporate formalities and the requirements of various patent offices.

87. Lindeman PLLC referred to its client as “Islet/BHV” and dealt directly with Islet regarding the Remo Formulation PCT application.

88. As a direct result of Islet’s financial, strategic, and other support, all of BHV’s necessary PCT national phase applications for the Remo Formulation delivery mechanism that comprises a key component of the Remo Technology were filed on time, resulting in issued patents for the Remo Formulation in at least Great Britain, Germany, Hong Kong, Canada, Australia, Israel, Mexico, South Africa, and Turkey, as well as additional pending patent applications, including in the United States (collectively PCT/2011/043143 and its progeny, the “BHV Patents”).

89. BHV also benefitted from having Islet lend to BHV the valuable goodwill and credibility in drug development that Islet had painstakingly built as a public company working with respected institutions such as UCLA, Yale, the National Institutes of Health, the University of Virginia, and other prestigious academic and U.S. government institutions such as the Department of Veterans Affairs.

90. This goodwill was especially valuable to the preservation of BHV’s license from Kissei. BHV had made little progress toward commercialization of a drug since entering into its agreement with Kissei in 2009, had not achieved a single milestone, had failed to advance U.S. patent protection other than filing a provisional application, and had committed to an expensive and onerous PCT patent approach without the necessary funds and other resources. Kissei had good reason to question whether BHV was meeting its obligations as licensee.

91. For obvious reasons, Kissei was highly enthusiastic about the idea of BHV partnering with Islet. For example, in an email dated November 7, 2012, Green told Steel that during Green and Wilkison’s most recent trip to Japan (funding for which Islet provided), Kissei



had approved BHV's decision to partner with Islet, and stated that it "is very excited about the Islet technologies, ... possible synergies, ... and explor[ing] collaborating on [another product]."

92. Indeed, BHV was able to use the arrangement with Islet to persuade Kissei to forgive \$100,000 of the clinical fee reimbursement that BHV owed to Kissei, and to accept an extended payment plan for the remainder, with the first payment to be made 45 days following the BHV-Islet transaction.

93. Islet also made other contributions toward development of the Remo Formulation. The New York offices of Islet and Islet's agents continued to serve as the central hub for the collaboration's joint efforts to develop Remo, as they had since Islet brought Wilkison and Green to New York for their initial meeting with Cheng. The parties had frequent meetings in 2012 and 2013 at the New York offices of Islet, MAXIM, and Islet's counsel.

94. Islet's consultant, Dr. Mende, was made freely available to BHV, and worked extensively with Green and Wilkison in connection with the patent filings and general commercialization of the Remo Technology, while Steel and others at Islet strategized with BHV on the joint venture.

95. Islet committed the bulk of its attention and resources to the Remo Technology at the expense of cultivating other products and licensed technologies.

96. Islet also agreed to pay the collaboration's patent-related expenses:

(a) Islet agreed to pay Lindeman PLLC (invoiced to Islet's New York office) for prosecuting the Remo patents. These bills included U.S. and foreign legal expenses and out of pocket costs, totaling over \$55,000 in only the first six months of collaboration.

(b) Islet also paid over \$100,000 in cash and stock to Islet consultants for technical services related to the Remo Technology and prosecution of the BHV patents.

**HAVING BEEN ENRICHED, GREEN AND WILKISON NEVER SHARE THE  
BENEFIT WITH ISLET**

97. In December 2012, Steel and Green reviewed a draft press release to publicly announce BHV and Islet's collaboration to develop the Remo Technology.

98. But once BHV's deadline of January 9, 2013 to enter the national phase stage under the PCT application deadline had safely passed, Green and Wilkison's behavior began to change.

99. On January 14, 2013, in advance of a call to discuss the "JV," Green emailed Islet saying that instead of the division of profits being made on an 80/20 basis according to the members' capital accounts as per the Term Sheet and LLC Agreement, Green believed BHV should receive 20 percent of all distributions, regardless of how much or little it had actually contributed.

100. BHV also demanded that BHV be able to reclaim exclusive control of the Kissei license from the joint venture, if at some point in the future BHV decided that Islet was not doing enough to develop the Remo Technology or a Kissei milestone payment were missed at any stage.

101. Surprised, Islet emphasized to BHV through its counsel that it had not agreed, and would not agree, to any arrangement whereby Islet would continue to subsidize the development of the Remo Technology for months and years, but could end up with no rights to the Remo Technology.

102. Nevertheless, in October 2013, Islet gave Green and Wilkison executive roles at Islet, as had been contemplated in in the Term Sheet and limited liability agreement. In advance of assuming those roles, the parties agreed that they should "pre-negotiate" the terms of BHV's sub-license, to avoid any conflict of interest, although Green and Wilkison stated that they did

not want to actually effectuate the sub-license until after BHV concluded another business matter.

103. On October 29, 2013, Green expressed his view in an email that during a conference call the parties had agreed to “the financial/business terms” for “the BHV/ISLT license to remogliflozin,” and Islet confirmed that it had the same understanding.

104. Despite this confirmation, however, BHV thereafter repeatedly demanded new, onerous terms and conditions in derogation of the existing agreement – notwithstanding that Islet was the party that had made possible BHV’s continued ownership of the Remo Technology, Kissei License, and BHV Patents in the first place, and Islet had also made BHV’s owners highly compensated executives of Islet. With no alternative, Islet (of which Green and Wilkison were now CEO and Chief Scientific Officer, respectively, and Green now also a member of the board), continued to negotiate with BHV.

105. In stark contrast to the 80/20 business terms on which it had agreed in 2012 in order to induce Islet to bail it out, BHV’s subsequent proposals – none of which resulted in any currently effective agreement – all shared the common characteristic of being far more favorable to BHV.

106. For example, in one proposed merger structure, the terms were so one-sided in favor of BHV that the U.S. Securities and Exchange Commission raised concerns, and Islet’s shareholders refused to approve the merger (resulting in termination of the transaction).

107. In another proposal, BHV yet again offered to allow Islet to sub-license BHV’s license from Kissei – but now BHV demanded that Islet pay \$5 million up front, and raise an additional \$10 million in outside capital, before BHV would effectuate the sub-license.

108. Meanwhile, BHV continued to benefit from investment of further Islet resources in the Remo Technology, which Islet prioritized over the other development opportunities in its portfolio.

**BHV ALONE IS ENRICHED BY THE BENEFIT ISLET PROVIDED**

109. On September 24, 2015, Islet's shareholders removed Green and Wilkison from Islet's board of directors.<sup>4</sup> At that time, Islet's stock was trading at just over \$0.08 per share. The company's stock never recovered; the price generally remained below \$0.10 per share until the company's stock ceased being publicly traded in 2017. In contrast, on July 31, 2012 (at the time Islet first met BHV), the stock was trading at \$1.40 per share.

110. BHV's fate has been far different.

111. On March 31, 2016, Avolynt, where Green and Wilkison are executives, announced that it had acquired BHV.

112. BHV (now an Avolynt subsidiary) continues to exploit the Remo Technology that Islet enabled BHV to retain.

113. On August 14, 2017, the Remo Formulation entered Phase 3 trials in India for use in treating type 2 diabetes mellitus.

114. It is likely that a treatment for type 2 diabetes using the Remo Formulation will be approved soon after the completion of the Phase 3 trials.

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<sup>4</sup> In December 2015, Islet commenced an action against Green and Wilkison (and BHV in the State of North Carolina, Superior Division, seeking relief for acts committed by Green and Wilkison during the course of their employment as directors and officers of Islet from October 2013 onward. Islet's claims against BHV for aiding and abetting breach of fiduciary duty and unjust enrichment were dismissed without prejudice for failure to state a claim by order dated January 12, 2017. Islet's claims for unjust enrichment against Green and Wilkison were likewise dismissed without prejudice by separate order of the same date, for failure to state a claim under North Carolina law and as duplicative of claims for breach of fiduciary duty and constructive fraud. Islet's remaining claims for breach of fiduciary duty and constructive trust against Green and Wilkison, and against them and BHV for constructive trust as to any assets transferred to it by Green and Wilkison while officers and directors of Islet, were dismissed with prejudice on August 29, 2017, as a sanction based on the finding that "Islet's claimed inability to pay [did] not excuse its failure" to advance defense costs to Green and Wilkison under the terms of their employment agreements with Islet.

115. In 2017 alone, approved SGLT2 inhibitors from AztraZeneca, Lilly & Boeegringer, and Johnson & Johnson collectively resulted in over \$2.5 billion in revenue. Remo, as a best in class SGLT2 inhibitor, could capture a significant portion of that market.

116. None of this would have been possible without the lifeline Islet gave to BHV in 2012 and 2013 to preserve and acquire international patent coverage for its Remo Formulation and to retain the Kissei License.

## **COUNT I**

### **BREACH OF CONTRACT**

117. Islet realleges paragraphs 1 through 116 as if fully set forth herein.

118. Islet and BHV agreed to enter into a joint venture for the purpose of jointly exploiting the Kissei License and the Remo Technology, with each agreeing to make contributions to the venture, to share in profits and debts, and to exert control.

119. Islet performed its obligations in significant part by providing BHV the money, strategic support, and goodwill it needed during a period of critical patent filings, avoiding a catastrophic loss of central BHV business assets – the patents on a biphasic delivery system for the Remo Technology, and BHV's relationship with Kissei.

120. Islet also agreed to, and did, offer Green and Wilkison executive positions at Islet.

121. BHV agreed that in consideration for the support Islet provided, Islet would receive an 80 percent ownership interest and 80 percent of proceeds from the commercialization of the Remo Technology.

122. But after its critical period of patent filings passed, BHV refused in bad faith to reduce the agreement to a final and formal writing, instead demanding that Islet agree to new, onerous, and substantially different terms and conditions.

123. BHV refused to honor its agreement to collaborate with Islet in exchange for an interest in the Remo Technology, or the proceeds thereof.

124. Islet has suffered damages as a result of these breaches in an amount that is presently unknown to Islet and will be determined at trial, consisting of, among other things and without limitation, a share of the ownership of and/or the profits earned on commercializing the Kissei License and BHV Patents, as well as the monies expended by Islet for the benefit of BHV.

## **COUNT II**

### **BREACH OF FIDUCIARY DUTY**

125. Islet realleges paragraphs 1 through 124 as if fully set forth herein.

126. As a consequence of their partnership, BHV owed Islet fiduciary duties, including duties of care, good faith, honesty, and loyalty.

127. BHV breached its fiduciary duties by, among other things, attempting to keep the Remo Technology for itself rather than contribute it to the joint venture as agreed, and by failing to disclose to Islet that it did not intend to perform their agreement to make contributions and share profits and losses, but rather intended to allow BHV to drain Islet's resources at Islet's expense without recompense.

128. As a direct and proximate consequence of these breaches of fiduciary duty, Islet has suffered damages in an amount that is presently unknown to Islet and will be determined at trial, consisting of, among other things and without limitation, a share of ownership of and/or the profits earned on commercializing the Kissei License and BHV Patents, as well as the monies expended by Islet for the benefit of BHV.

### **COUNT III**

#### **UNJUST ENRICHMENT**

(In the Alternative)

129. Islet realleges paragraphs 1 through 128 as if fully set forth herein.

130. Islet provided Green, Wilkison, and BHV with funding; provided scientific assistance, and managed the prosecution of the patents necessary for providing a biphasic implementation of the Remo Technology both in the U.S. and around the world; and Islet allowed Green, Wilkison, and BHV to use its goodwill in the pharmaceutical industry to preserve and advance BHV's relationship with Kissei.

131. Green, Wilkison, and BHV were enriched by the benefits Islet provided: Islet incurred certain expenses of Green, Wilkison, and BHV throughout the process of developing and commercializing the Remo Technology; Islet's experts provided scientific assistance on the BHV Patents to ensure their successful protection; Islet incurred expenses for and managed the patent prosecution process, successfully prosecuting patents around the world, even though before Islet's involvement, Green, Wilkison, and BHV were at risk for patent abandonment given BHV's lack of financial resources; and, after Islet became involved, solidifying BHV's relationship with Kissei, which preserved the Kissei License and was manifested in at least Kissei's agreement to both reduce the debt BHV owed Kissei and permit a repayment plan.

132. Green, Wilkison, and BHV knew that Islet had requested, and obtained, "agreed terms" for a partnership in the Remo Technology before the benefits were conferred.

133. Green, Wilkison, and BHV promised Islet a substantial portion of the ownership of and/or profits from the commercialization of the Kissei License and Remo Technology, including the BHV Patents, if Islet collaborated with Green, Wilkison, and BHV to successfully develop this class of SGLT2 products.

134. Green, Wilkison, and BHV had no cause to believe, and could not reasonably have believed, that Islet, itself a public company with limited funds and other resources, was committing a significant portion of those funds and resources to Green, Wilkison, and BHV, and was permitting its goodwill to be used to assure BHV's licensor Kissei, gratuitously and without expectation of the promised interest in the Remo Technology's future performance.

135. Islet contributed to the preservation of Green's, Wilkison's, and BHV's property and to increasing its value greatly by obtaining patent protection, committing monies, providing strategy, and sharing valuable goodwill and other early-stage support typical of biotech investors whose business practice is to provide such support in exchange for a share of ownership, profits, or both.

136. Green, Wilkison, and BHV accepted the benefits Islet provided without advising Islet that it had no intention of allowing Islet to reap any of the benefit of the asset that Islet was cultivating, or of making good on its agreement to effect a partnership in interest or joint venture.

137. To the contrary, Green, Wilkison, and BHV repeatedly assured Islet that BHV intended to provide Islet with a way to profit from the proceeds of the Remo Technology.

138. Equity and good conscience should not permit Defendants to unilaterally retain the benefits that Green, Wilkison, and BHV received from Islet, including not only expenses incurred on behalf of BHV, but the preservation of the Kissei relationship and BHV Patents, and the increase in the value of the Remo Technology for which Islet was responsible.

139. Defendants are therefore liable to Islet for unjust enrichment under New York law. Islet is entitled to a share of the ownership of the Kissei License and BHV Patents (and other aspects of the Remo Technology), and to otherwise avoid Defendants' unfair gain.



**COUNT IV**

**FRAUD**

(In the Alternative)

140. Islet realleges paragraphs 1 through 139 as if fully set forth herein.

141. When Green, Wilkison, and BHV critically needed business resources from Islet, they promised Islet 80 percent of the ownership of and/or the profits from the commercialization of the Kissei License and BHV Patents, and to negotiate in good faith to finalize an agreement based on those terms.

142. But this was a material misrepresentation; Green, Wilkison, and BHV never intended to let Islet reap those benefits as joint venturers or negotiate a joint venture agreement in good faith, and falsely represented their intent when the Term Sheet was made and throughout the parties' discussions to enter into an agreement to collaborate on the Remo Technology.

143. Green and Wilkison did not correct Islet's belief that BHV was proceeding to negotiate on that basis, and induced Islet to continue to fund and support the prosecution of the BHV Patents.

144. Islet reasonably relied on Green and Wilkison's promises, and never would have provided critical resources to Green, Wilkison, and BHV if Islet knew they were planning to appropriate Islet's resources for their own benefit and refuse to provide Islet the benefits they had promised to elicit Islet's support.

145. Green, Wilkison, and BHV knew at all times that their representations were false and intended for Islet to rely on the representations and/or omissions to its detriment.

146. Islet justifiably relied on Defendants' misrepresentations, and omissions to its detriment and has been damaged as a result.

**COUNT V**

**CONSTRUCTIVE TRUST**

(In the Alternative)

147. Islet realleges paragraphs 1 through 146 as if fully set forth herein.

148. By reason of the conduct described above, Defendants wrongfully obtained and have wrongfully retained ownership and control over the BHV Patents, the Kissei License, and the profits to be received from commercializing this intellectual property.

149. Defendants' wrongful exertion of ownership and control over the BHV Patents and the Kissei License, and the profits to be received therefrom, is in derogation to the rights Islet obtained and was to obtain in the commercialization of this intellectual property.

150. By reason of the foregoing, Islet requests the imposition of a constructive trust upon the BHV Patents, the Kissei License, and the other aspects of the Remo Technology, the measure of such trust to be adduced at trial.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. A judgment that the ownership of and/or profits earned from commercializing the BHV Patents and Kissei License, and other aspects of the Remo Technology, belongs in part to Islet to avoid the unjust enrichment of BHV, Green, and Wilkison;

B. The imposition of a constructive trust in favor of Islet over the BHV Patents, the Kissei License, and the profits therefrom;

C. An award of damages to be determined at trial, consisting of, among other things and without limitation, a share of the ownership of and/or the profits earned on commercializing the Kissei License and BHV Patents, and other aspects of the Remo Technology, and avoidance

of Defendants' unfair gain, as well as the monies expended by Islet for the benefit of BHV, Green, and Wilkison; and

D. All other and further relief as the Court deems just and proper.

**JURY DEMAND**

Islet hereby demands a trial by jury on all issues of fact and damages stated herein.

Dated: April 4, 2019  
New York, New York

**COHEN & GRESSER LLP**

/s/ Francisco Villegas  
Alexandra Wald  
awald@cohengresser.com  
Francisco A. Villegas  
fvillegas@cohengresser.com  
Marvin J. Lowenthal  
mloenthal@cohengresser.com  
800 Third Avenue, 21<sup>st</sup> Floor  
New York, NY 10022  
Phone: (212) 957-7600  
Fax: (212) 957-4514

*Attorneys for Plaintiff Islet Sciences, Inc.*